

EXHIBIT O

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 CP1998SEF001
 Appendix I

PRODUCT DEVICE DESIGN SAFETY ASSESSMENT (DDSA) APPROVAL PAGE

DESIGN SAFETY ASSESSMENT		REVISION: C	
		REVISION DATE: 2/25/2005	
Product Name:		GYNECARE PROLIFT* PELVIC FLOOR REPAIR SYSTEM (PROJECT D'ART)	
Product Code: <i>The following matrix identifies the current product codes for the Gynecare PROLIFT* Pelvic Floor Repair System. The risk assessment is conducted on product code PFRT01 that is inclusive of all components herein referenced.</i>	Product Code	Product Description	
	PFRT01	PROLIFT Total Pelvic Floor Repair System	
	PFRA01	PROLIFT Anterior Pelvic Floor Repair System	
	PFRP01	PROLIFT Posterior Pelvic Floor Repair System	
RMC:		N/A	
Project Leader:		Scott Ciarrocca	
ANALYSIS TEAM		ASSOCIATE NAME	
Development Engineer/Scientist:		Rod Simpson	
Manufacturing/Technical Services Engineer:		Sunny Rha	
Quality Assurance Engineer:		Jeffrey Everett	
Regulatory Affairs:		Sean O'Bryan	
Other:		N/A	
DISPOSITION/APPROVAL:			
Approved in ECCS. Electronic approval indicates an answer of "Yes" to the following question:		I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device design to be safe for use	

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DEVICE DESIGN SAFETY ASSESSMENT (DDSA) SUMMARY REPORT
(Revision C)

DEVICE: (Provide a description of the overall device system):

The GYNECARE PROLIFT Total, Anterior, and Posterior Pelvic Floor Repair Systems consist of pre-cut GYNECARE GYNEMESH* PS Nonabsorbable PROLENE* Soft Mesh implants and a set of instruments to facilitate mesh implant placement. The following table summarizes the instruments included with each system:

REPAIR SYSTEM	COMPONENTS			
	Mesh Implant	Guide	Retrieval Devices	Cannulas
Total Pelvic Floor Repair System	1 Total	1	6	6
Anterior Pelvic Floor Repair System	1 Anterior	1	4	4
Posterior Pelvic Floor Repair System	1 Posterior	1	2	2

Table 1 – GYNECARE PROLIFT Pelvic Floor Repair System Components

GYNECARE GYNEMESH PS

GYNECARE GYNEMESH PS is mesh constructed of knitted filaments of extruded polypropylene identical in composition to PROLENE Polypropylene Suture, Nonabsorbable Surgical Sutures, U.S.P. (ETHICON, INC.). This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use. The mesh affords excellent strength, durability, and surgical adaptability, with sufficient porosity for necessary tissue ingrowth. Blue PROLENE monofilaments have been incorporated to produce contrast striping in the mesh. The mesh is constructed of reduced diameter monofilament fibers, knitted into a unique design that results in a mesh that is approximately 50 percent more flexible than standard PROLENE mesh. The mesh is knitted by a process which interlinks each fiber junction and which provides for elasticity in both directions. This construction permits the mesh to be cut into any desired shape or size without unraveling. The bi-directional elastic property allows adaptation to various stresses encountered in the body.

Total Mesh Implant

The Total mesh implant is constructed from GYNECARE GYNEMESH PS and is shaped for performing a total vaginal repair. The implant has 6 straps: 4 for securing the anterior portion of the implant via a transobturator approach and two for securing the posterior portion of the implant in the sacrospinous ligament via a transgluteal approach. Alternatively, the 2 posterior straps may be cut to reduce their length and secured in the sacrospinous ligament via a vaginal approach. The proximal and distal anterior straps have squared and triangular ends, respectively, while the posterior straps have rounded ends.

Anterior Mesh Implant

The Anterior mesh implant is constructed from GYNECARE GYNEMESH PS and is shaped for repair of anterior vaginal defects. The implant has 4 straps that are secured via a transobturator approach. The proximal and distal anterior straps have squared and triangular ends, respectively.

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Posterior Mesh Implant

The Posterior mesh implant is constructed from GYNECARE GYNEMESH PS and is shaped for repair of posterior and/or apical vaginal vault defects. The implant has 2 straps that are secured in the sacrospinous ligament via a transgluteal approach. Alternatively, the 2 posterior straps may be cut to reduce their length and secured in the sacrospinous ligament via a vaginal approach. The posterior straps have rounded ends.

GYNECARE PROLIFT Guide

The GYNECARE PROLIFT Guide is a single-patient-use instrument designed to create tissue paths to allow placement of the Total, Anterior, and Posterior mesh implants and to facilitate placement of the GYNECARE PROLIFT Cannula. Its length and curvature are specifically designed to create proper placement paths for all mesh implant straps. The GYNECARE PROLIFT Guide is suitable for use on both sides of the patient.

GYNECARE PROLIFT Cannula

The GYNECARE PROLIFT Cannula is a single-patient-use instrument used in conjunction with the GYNECARE PROLIFT Guide to facilitate passage of the implant straps while protecting the surrounding tissue. Each GYNECARE PROLIFT Cannula is placed over the GYNECARE PROLIFT Guide prior to passage and remains in place after the GYNECARE PROLIFT Guide is withdrawn.

GYNECARE PROLIFT Retrieval Device

The GYNECARE PROLIFT Retrieval Device is a single-patient-use instrument designed to facilitate placement of the mesh implant straps. The GYNECARE PROLIFT Retrieval Device is passed through the previously positioned GYNECARE PROLIFT Cannula until its distal end is retrieved through the vaginal dissection. The distal end of the GYNECARE PROLIFT Retrieval Device has a loop to securely capture the mesh implant strap as the strap is drawn out through the GYNECARE PROLIFT Cannula.

SCOPE of the DESIGN SAFETY ASSESSMENT: (Define the scope of this risk assessment)

This risk assessment was completed on (*check one*): ☒ Device ☐ Subsystem ☐ Component

This risk assessment was completed on the GYNECARE PROLIFT Total Pelvic Floor Repair Systems' design as of 02/25/2005.

Define the intended use of the reviewed item:

The GYNECARE PROLIFT Total, Anterior, and Posterior Pelvic Floor Repair Systems are indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.

Briefly describe the revision to the device or sub-system, which preceded a revision to the DDSA:

Revision C of this document is the final product DDSA. No significant design changes have occurred since revision B (12/10/2005) that incorporated the addition of MED6015 Silicone elastomer 'plugs' on the retrieval device. This revision includes updates to all appendices as relevant to the final design. Design FMEA, Application FMEA, and Control Plans of the product are located in the Gynecare PROLIFT design history file (DHF-0000105), which is retained in the Electronic Design History File (eDHF), Somerville, NJ.

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** {To be completed for Conceptual DDSA on a complete device system; Review and update as needed on subsequent revisions.}

Medical Impact: Describe the current standard of care treatment/therapy:

Little agreement about the “standard of care” for vaginal defects currently exists. Surgical approach (e.g. abdominal, vaginal, laparoscopic), material (mesh, suture, biological), and surgical technique variations are widely reported in the literature. There is no current “standard of care” for managing vaginal defects.

Describe the medical impact/benefit imparted to the current standard of care by the device system:

A simple, unified approach for the repair of all pelvic floor defects is offered by this system (mesh implants, guides, cannulas, and retrieval devices). This represents a combination and optimization of techniques that have evolved and are now combined to address the totality of vaginal repair procedures. The mesh and similar guides have previously been used for vaginal repair procedures.

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CHARACTERISTIC	ISSUE	RESPONSE		COMMENT
		N/A	YES	
1 Intended Use	1) Is special training of the intended user needed?		Yes	If yes, please attach training plan Professional Education program has been developed.
	2) Does use of the device impose any ergonomic factors or effects?	N/A		If yes, please attach plan.
	3) Are there any environmental factors that could influence safety/function of the device?	N/A		If yes, please define the limits.
	4) Can the patient control or influence the use of the device?		Yes	If yes, please define the training plan for the user. Professional Education program has been developed.
	5) Is device safety/functionality compromised based upon the patient (such as elderly, diabetic, handicapped, or other)?		Yes	If yes, please define the nature of the compromise and the limits. Instructions for use (IFU) state Contraindications: "When GYNEMESH PS mesh is used in infants, children, pregnant women, or women planning future pregnancies, the surgeon should be aware that this product will not stretch significantly as the patient grows."
2 Patient Contact	6) Does device use utilize surface contact to the patient?		Yes	If yes, please define the length and frequency of contact. All PROLIFT Pelvic Floor Repair System components have transient surface contact on the order of minutes.

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CHARACTERISTIC		ISSUE		RESPONSE		COMMENT
				N/A	YES	
		7) Does device use utilize invasive contact with the patient?			Yes	<p>If yes, please define the length and frequency of contact.</p> <p>All following PROLIFT Pelvic Floor Repair System components utilize invasive contact: (based on Total repair)</p> <ul style="list-style-type: none"> • Guide – transient for <30 minutes • Cannula – invasive placement for <60 minutes • Retrieval line – transient for <60minutes • Mesh – See #8 below.
		8) Does device use require implantation?			Yes	<p>If yes, please define the length and frequency of contact.</p> <p>GYNE MESH PS mesh is a permanent implant.</p>
3	Materials	9) Define the materials utilized in the construction of the device. Highlight those materials that will involve direct patient contact			Yes	<ul style="list-style-type: none"> • Guide <ul style="list-style-type: none"> • <u>Handle</u> – Polycarbonate • <u>Needle</u> – Stainless Steel 316 LVM • Cannula <ul style="list-style-type: none"> • <u>Cannula</u> - Pebax and TiO₂ • <u>Hub</u> - Pebax and TiO₂ • Retrieval line <ul style="list-style-type: none"> • <u>Monofilament</u> –Polypropylene • <u>Heat Shrink</u> – Polyolefin • <u>Seal</u> – Silicone elastomer (MED6015) • Mesh <ul style="list-style-type: none"> • <u>GYNECARE GYNE MESH PS mesh</u> – PROLENE Polypropylene

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CHARACTERISTIC	ISSUE	RESPONSE		COMMENT
		N/A	YES	
	10) Have the materials been tested for toxicity and biocompatibility?		Yes	If yes, please identify where the file(s) are located. • Cannula, Guide, Retrieval Device – Reference Gynecare PROLIFT eDHF (DHF0000105) • Mesh – Reference GYNECARE GYNEMESH PS mesh DHF #0956
	11) Have the materials been tested for carcinogenicity, teratology, and mutagenicity (as appropriate)?		Yes	If yes, please identify where the file(s) are located. • Cannula, Guide, Retrieval Device - Reference Gynecare PROLIFT eDHF (DHF0000105) • Mesh – Reference GYNECARE GYNEMESH PS mesh DHF #0956
	12) Is the strength of load-bearing materials sufficient for the intended use?		Yes	If yes, please attach test data or engineering analysis Reference Gynecare PROLIFT eDHF (DHF0000105), Design Verification
4 Energy	13) Is energy delivered to and/or extracted from the patient?	N/A		If no, proceed to the next section.
	14) Describe the type of energy transferred.	N/A		
	15) Is the energy output is controlled, in terms of quality, quantity, and time-function	N/A		
5 Substances	16) Are substances delivered to and/or extracted from the patient?	N/A		If no, proceed to the next section.

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CHARACTERISTIC	ISSUE	RESPONSE		COMMENT
		N/A	YES	
	17) Is the device absorbable?	N/A		If yes, please attach a listing of all by-products produced during the devices in-situ degradation
	18) If the device is absorbable, have all of the materials identified above been tested for biocompatibility at the appropriate concentrations?	N/A		If yes, please identify the location of appropriate reports.
	19) Is the transfer rate (delivery/extraction) of substances controlled?	N/A		If yes, please describe how the transfer rate is controlled.
	20) What is the maximum/minimum substance transfer rate?	N/A		If appropriate, please attach required information.
6 Biological Materials	21) Are biological materials processed by the device for subsequent re-use?	N/A		If not, proceed to the next section.
	22) Is the device disposable?	N/A		
	23) Are those components contacting biological materials cleanable and sterilizable?	N/A		If yes, please specify location of reports.
	24) Are those components contacting biological materials compatible?	N/A		If yes, please specify location of reports.
7 Sterility - Supplied Sterile	25) Is the device supplied sterile?		Yes	If not, please proceed to the next section. PROLIFT Pelvic Floor Repair System is provided sterile.
	26) Identify the method of sterilization	N/A		Please specify location of report. Method of Sterilization: Ethylene Oxide

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CHARACTERISTIC	ISSUE	RESPONSE		COMMENT
		N/A	YES	
				Reference Gynecare PROLIFT eDHF (DHF0000105); Sterilization Validation
	27) Is the sterilization method compatible with the materials?		Yes	If yes, please specify location of reports. <u>Guides, Cannula, Retrieval lines</u> – Reference Gynecare PROLIFT eDHF (DHF0000105); Biocompatibility, Stability, Design Verification. <u>Mesh</u> – Reference GYNECARE GYNEMESH PS mesh DHF #0956
	28) Are the materials stable after sterilization?		Yes	If yes, please specify location of reports. <u>Guides, Cannula, Retrieval lines</u> – Reference Gynecare PROLIFT eDHF (DHF0000105); Stability <u>Mesh</u> – Reference GYNECARE GYNEMESH PS mesh DHF #0956
	29) Is the device design sterilizable?		Yes	If yes, please specify location of reports. Reference Gynecare PROLIFT eDHF (DHF0000105); Sterilization Validation
	30) Is the package designed to provide for sterilization of the device?		Yes	If yes, please specify location of reports. Reference Gynecare PROLIFT eDHF (DHF0000105); Sterilization Validation, Packaging (Transit) testing
	31) Has the shelf life of the system been determined?		Yes	If yes, please specify location of reports. Reference Gynecare PROLIFT eDHF (DHF0000105); Stability

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CHARACTERISTIC		ISSUE		RESPONSE		COMMENT
				N/A	YES	
						<ul style="list-style-type: none"> <u>Launch</u>: Minimum 1 year shelf-life based on accelerated stability
		32) Is the device re-usable?		N/A		If not, please proceed to the next section.
		33) Are there limitations to the number of re-use cycles?		N/A		If yes, please specify location of reports.
		34) Are there restrictions to sterilization methods utilized by the user of the device?		N/A		If yes, please specify location of reports.
8 Sterility - Supplied Non-Sterile		35) Is the device to be sterilized by the user?		N/A		If not, please proceed to the next section.
		36) Is the method of sterilization and cycle parameters defined?		N/A		If yes, please specify location of reports.
		37) Is the packaging of the product during sterilization specified?		N/A		If yes, please specify location of reports.
		38) Does sterilization validation data exist for the recommended sterilization cycle?		N/A		If yes, please specify location of reports.
		39) Were other methods of sterilization examined?		N/A		If yes, please specify location of reports.
		40) Has the shelf life of the system been determined?		N/A		If yes, please specify location of reports.
9 Environment		41) Is the device intended to modify the patient environment?		N/A		If not, please proceed to the next section.
		42) What is the effect of temperature on the system performance?		N/A		If yes, please specify location of reports.

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CHARACTERISTIC	ISSUE	RESPONSE		COMMENT
		N/A	YES	
	43)What is the effect of humidity on the system performance?	N/A		If yes, please specify location of reports.
	44)What is the effect of atmospheric gas concentration on system performance?	N/A		If yes, please specify location of reports.
	45)What is the effect of pressure on system performance?	N/A		If yes, please specify location of reports.
10 Measurements	46)Does the device make measurements?	N/A		If not, please proceed to the next section.
	47)Is there interference of the desired parameter with other possible measurements?	N/A		If yes, please specify location of reports.
	48)Is the accuracy of the measurement known at point of use?	N/A		What is the accuracy?
	49)Is the precision of the measurement known?	N/A		What is the precision?
11 Interpretive	50)Are conclusions presented by the device based upon measurements, input, or acquired data?	N/A		If yes, please specify location of software validation reports.
12 Interactions	51)Is the device intended to control or interact with other devices or drugs?	N/A		If not, please proceed to the next section.
	52)If the device is used with other devices or drugs, is there a potential interaction?	N/A		If yes, please specify
	53)Does the interaction render any safety or functional changes to the device?	N/A		If yes, please specify
	54)Does the interaction render any safety or functional changes to the other device?	N/A		If yes, please specify

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CHARACTERISTIC	ISSUE	RESPONSE		COMMENT
		N/A	YES	
13 Extraneous Unwanted Energy or Substances	55) Are there any unwanted outputs of energy or substances?	N/A		If not, please proceed to the next section.
	56) Does noise affect the device output?	N/A		If yes, please define the limits.
	57) Does vibration affect the device output?	N/A		If yes, please define the limits.
	58) Does heat affect the device output?	N/A		If yes, please define the limits.
	59) Does ionizing radiation affect the device output?	N/A		If yes, please define the limits.
	60) Does non-ionizing radiation affect the device output?	N/A		If yes, please define the limits.
	61) Does UV/visible/IR radiation affect the device output?	N/A		If yes, please define the limits.
	62) Do leakage currents affect the device output?	N/A		If yes, please define the limits.
	63) Do electric/magnetic fields affect the device output?	N/A		If yes, please define the limits.
	64) Do contact temperatures affect the device output?	N/A		If yes, please define the limits.
	65) Does discharge of chemicals affect the device output?	N/A		If yes, please define the effect.
	66) Does discharge of waste products affect the device output?	N/A		If yes, please define the effect.
	67) Does discharge of body fluids affect the device's output?	N/A		If yes, please define the effect.

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CHARACTERISTIC	ISSUE	RESPONSE		COMMENT
		N/A	YES	
14 Environmental Influences	68) Is the device susceptible to environmental influences?	N/A		If not, please proceed to the next section.
	69) Do shipping temperatures affect device safety or functionality?	N/A		If yes, please state the limits.
	70) Does storage temperatures, humidity, or light affect device safety or functionality?	N/A		If yes, please state the limits.
	71) Does spillage on the device affect safety or functionality?	N/A		If yes, please state the limits.
	72) Do fluctuations in the power affect the device output or safety?	N/A		If yes, please state the limits.
	73) Does variation in the operating temperature, humidity, or light affect the device output or safety?	N/A		If yes, please state the limits.
	74) Does variation in the operating humidity affect the device output of safety?	N/A		If yes, please state the limits.
15 Accessories	75) Are there essential consumables or accessories associated with the device?	N/A		If yes, please specify PROLIFT Pelvic Floor Repair System includes all essential consumables (outside of standard surgical accessories.) Reference Gynecare PROLIFT eDHF (DHF0000105); Design Validation
16 Preventative Maintenance	76) Is preventative maintenance necessary?	N/A		If not, please proceed to the next section.
	77) Can the operator perform preventative maintenance?	N/A		
	78) Is a specialist needed to perform preventative maintenance?	N/A		

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CHARACTERISTIC	ISSUE	RESPONSE		COMMENT
		N/A	YES	
17 Calibration	79) Is calibration necessary?	N/A		If not, please proceed to the next section.
	80) Can the operator calibrate the device?	N/A		
	81) Is an external calibration of the device needed?	N/A		
	82) Is the calibration frequency defined?	N/A		
18 Software	83) Does the device contain software?	N/A		If not, please proceed to the next section.
	84) Can the operator access the software code?	N/A		
	85) Are there means to prevent the operator from modifying the code?	N/A		
19 Shelf-life	86) Does the device have a restricted shelf life?		Yes	If not, please proceed to the next section.
	87) Does the package contain an indicator for stability?		Yes	Package will contain an expiry date as an indicator of stability. The PROLIFT Pelvic Floor Repair System kit expiry will be based on the shortest expiry date of the kit components.
20 Long-term Effects	88) Is there any delayed or long-term user effect?	N/A		If yes, please specify.
21 Mechanical Forces	89) **Is the device subjected to any mechanical forces?		Yes	If not, please proceed to the next section.
	90) **Are mechanical forces under the control of the user, or by interaction with other people?		Yes	If yes, please specify how the mechanical forces are controlled. All forces are under control (tactile) by the user.
22 Life-Time	91) **Identify the factors that affect the	N/A		Please specify factors

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CHARACTERISTIC		ISSUE		RESPONSE		COMMENT
				N/A	YES	
		lifetime of the device, such as aging or battery depletion.				affecting expected usable life of the device. <u>Guides, Cannula, Retrieval lines</u> – Expiry date <u>Mesh</u> – Lifetime factors not applicable for Nonabsorbable implant.
23 Disposal		92) **Is safe decommissioning or disposal of the device necessary?		N/A		If yes, please specify resultant waste products, toxic or hazardous materials. Device & packaging designed to be disposed through standard biohazardous materials and waste procedures. Reference Gynecare PROLIFT eDHF (DHF0000105); Johnson & Johnson Design for Environment (DfE)
24 Installation		93) **Does installation of the device require special training?		N/A		If yes, specify what prevents unskilled persons from installing the device.
25 Manufacturing		94) **Will this device require new manufacturing processes/technologies to be introduced into production?		N/A		If yes, define those potential hazards to be addressed through a process risk assessment.
26 Human Factors		95) **Is successful use of the device dependent upon human factors, such as the user interface?		N/A		If not, please proceed to the next section.
		96) **Does the device have connecting parts or accessories?		N/A		If yes, define the impact of making wrong connection, differentiation, similarity to other product's

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CHARACTERISTIC	ISSUE	RESPONSE		COMMENT
		N/A	YES	
				connections, connection force, feedback or connection integrity, impact of over- or under-tightening.
	97) **Does the device have a control interface?	N/A		If yes, address the following issues: spacing, coding, grouping, mapping, modes of feedback, blunders, slips, control differentiation, visibility, direction of activation or change, are controls continuous/discrete, are actions/settings reversible.
	98) **Does the device display information?	N/A		If yes, address the following issues: visibility in various environments, orientation, populations and perspectives, clarity and accessibility of information.
	99) **Is the device controlled by a menu?	N/A		If yes, address the following issues: complexity and number of layers, awareness of state, location of settings, navigation methods, number of steps per action, sequence clarity and memorization issues, relationship of function to accessibility.

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		RESPONSE		COMMENT
CHARACTERISTIC	ISSUE	N/A	YES	
	100) **Is the device intended to be portable?	N/A		If yes, address the following issues: necessary grips, handles, wheels, brakes, mechanical stability, durability.
	ADD ADDITIONAL CHARACTERISTICS AS NEEDED			